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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/142,831
63431

Applicant(s)

Ulrich et al.

Examiner

Marianne P. Allen

Group Art Unit

1645



X Responsive to communication(s) filed on Aug 20, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) 1-70 and 100-109 is/are pending in the application.

Of the above, claim(s) 2, 3, 7-11, 15-17, 19, 20, 24-28, 32-36, 40-42, 45, 46 are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) 1, 4-6, 12-14, 18, 21-23, 29-31, 37-39, 43, 44, 47-49, 53, 56-58, 62, and 63 are rejected.

Claim(s) _____ is/are objected to.

X Claims 1-70 and 100-109 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

X Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s). 1

X Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claims 71-99 have been cancelled. Claims 100-109 have been newly added.

Applicant's election with traverse of Group II, claims 1, 4-6, 12-14, 18, 21-23, 29-31, 37-39, 43-44, 47-49, 53, 56-58, 62, and 65-67 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the inventions are classified in the same class and subclass. This is not found persuasive because the requirement for a non-coextensive literature search and the structural differences in the claimed inventions establishes the burden of search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-3, 7-11, 15-17, 19-20, 24-28, 32-36, 40-42, 45-46, 50-52, 54-55, 59-61, 63-64, 68-70, and 100-109 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **with** traverse in Paper No. 6.

Applicant is advised that generic claims 1, 18, 43-44, 53, and 62 have been examined on the merits only to the degree that they reflect the elected invention Staphylococcal enterotoxin B.

The disclosure is objected to because of the following informalities: The specification fails to reference or identify the SEQ ID NOS. disclosed in the sequence listing. It is further noted that the statement concerning submission of the CRF (Paper No. 2, dated 11/12/97) fails to indicate that the CRF and paper copy of the sequence listing are the same.

Appropriate correction is required.

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The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The recombinant DNA constructs pETA489270C, pETB2360210, and pETB899445P claimed in claims 37-39 do not appear to be disclosed in the specification. The composition of these constructs does not appear to be described. Applicant is requested to point to basis in the specification for these claims.

Claims 1, 4-6, 12-14, 18, 21-23, 29-31, 37-39, 43-44, 47-49, 53, 56-58, 62, and 65-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Notwithstanding applicant's statement that the newly submitted sequence listing contains no new matter, the new listing contains unexplained changes to the sequences when compared to the original listing.

For example, in the original listing SEQ ID NO: 10 has amino acid 20 as L (leucine) rather than Lys (lysine) and amino acid 171 as N (asparagine) rather than Asp (aspartate). In the original listing SEQ ID NO: 6 has amino acid 220 as E (glutamate) rather than Gln (glutamine) and amino acid 256 as I (isoleucine) rather than Leu (leucine). In addition the original listing has a serine (S) inserted between amino acids 221 and 222 of the present SEQ ID NO. In the original

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sequence listing amino acid 87 is N (asparagine) rather than Asp (aspartate), amino acid 177 is T (threonine) rather than Tyr (tyrosine), amino acid 220 as E (glutamate) rather than Gln (glutamine) and amino acid 256 as I (isoleucine) rather than Leu (leucine). In addition the original listing has a serine (S) inserted between amino acids 221 and 222 of the present SEQ ID NO.

Applicant is advised that the examiner has not made an exhaustive comparison of sequences for new changes introduced and that it is suggested that the sequence listing be carefully scrutinized for additional inconsistencies.

Should the above new matter rejection be overcome, at least the following enablement rejection would apply to the claims.

The enablement of claims 37-39 requires availability of the named DNA constructs. This determination has been made because the materials required to produce these constructs do not appear to be set forth in the specification and have not been shown to be publicly known and freely available. Accordingly, it is deemed that a deposit should have been made in accordance with MPEP 2402. In order to certify that the deposit meets the criteria set forth in MPEP 2402, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number. Applicant is advised that the Patent Office accepts Budapest approved deposits, as long as assurance is provided that the deposited materials will be made irrevocably available with no restrictions upon issuance of a patent.

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Claims 44, 47-49, 62, and 65-67 are directed to host cells and methods of producing altered superantigen toxins using the host cells. Because the claims do not indicate that these are isolated host cells the claims can be construed to encompass transgenic animals and methods of producing the toxins in transgenic animals. Such animals and methods do not appear to be disclosed nor enabled by the specification. It would not have been routine to produce toxins in this manner at the time of the invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 18, 43-44, 53, and 62 are rejected under 35 U.S.C. 102(a) as being anticipated by Bavari et al. (Vaccines 96).

The authorship of the reference is Bavari, Olson, Dyas, and Ulrich. The inventorship of the instant application is Ulrich, Olson, and Bavari. As such, this reference is by other within the meaning of 102(a) and valid prior art.

Bavari et al. disclose mutating the Staphylococcal enterotoxin B (SEB) in the hydrophobic loop, polar pocket, and disulfide loop to disrupt MHC class-II binding. (See figures 3-4 and page 138, refined vaccine structure.) Although not explicitly disclosed, production of these engineered

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vaccines would have required the claimed DNA fragments, expression vectors, host cells, and methods of production. The reference clearly relies upon standard site-directed mutagenesis and recombinant production techniques that would have been well known to one of ordinary skill in the art at the time of the invention. As such, the reference is deemed to anticipate the claims.

Claims 1, 18, 43-44, 53, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayball et al. (International Immunology, 1994).

Hayball et al. discloses the recombinant production of SEB in which positions 60 and 61 have been mutated and result in altered T cell receptor binding. (See abstract, methods at page 200, and Table 1.)

Claims 4-6, 12-14, 18, 21-23, 43-44, 53, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The specification does not appear to define what is meant by an "allelic portion." This does not appear to be an art accepted phrase. This is particularly true for claims 12-14 which refer to amino acid sequences. Alleles are with reference to the gene itself, not the encoded protein.

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Claim 18 is confusing in failing to indicate that the vector and DNA fragment are in any way associated with each other. It appears that a vector containing the DNA fragment may have been intended.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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